

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO: ALL WAVE 1 CASES listed in Exhibit A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS’ MOTION TO STRIKE DR. SHELBY F. THAMES’ SUPPLEMENTAL
REPORTS OR, IN THE ALTERNATIVE, FOR LEAVE TO FILE A *DAUBERT*
MOTION BASED ON THE FLAWED METHODOLOGY EMPLOYED THEREIN**

Plaintiffs move the Court to strike both of Ethicon’s untimely Intentional Oxidation of Prolene Mesh Supplemental Reports of Dr. Shelby F. Thames (the “Supplemental Reports”) dated August 8, 2016 and September 28, 2016. In the alternative, Plaintiffs ask for permission to file a *Daubert* motion based on the flawed methodology and any opinions derived therefrom.

ARGUMENT

This Motion seeks to strike Dr. Thames’ Supplemental Reports and any reference or reliance on them at trial. The deadline to serve expert reports in Wave 1 was March 2, 2016. Fourth Amended Wave 1 Docket Control Order [Doc. No. 2314] at 1. All discovery closed on this matter on April 1, 2016. *Id.* The deadline for *Daubert* motions was April 21, 2016, with response briefs to be filed by May 9, 2016, and reply briefs due on May 16, 2016. *Id.* at 2.

On August 8, 2016—over five months after the March 2 deadline—Ethicon served its first Supplemental Report from Dr. Thames on Plaintiffs in this consolidation.¹ Then on September 28, 2016—almost seven months after the March 2 deadline—Ethicon served its

¹ See Ex. B, Supplemental Report of Dr. Thames (August 8, 2016).

second Supplemental Report from Dr. Thames.² In both of these supplements, Dr. Thames asserts that he has performed additional testing and analysis on a sample of TVT mesh in an attempt to bolster his opinions and to provide additional information about the cleaning protocol that he used in this case. *See id.* Dr. Thames' opinions garnered from this additional testing and analysis are new and were not disclosed to Plaintiffs in his original expert report in this consolidation (because the testing had not yet been performed).³

Indeed, not only were Dr. Thames' Supplemental Reports served after the Court's March 2 deadline to disclose expert opinions, they were also served after the April 1 deadline for the close of all discovery, and the April 21 deadline to file *Daubert* motions. [Doc. No. 2314] at 1-2. The Court set clearly defined deadlines for expert disclosures to promote efficiency and preserve judicial resources. By attempting to interject new and additional expert opinions based on previously undisclosed testing and analyses, Ethicon seeks to undermine that purpose.

This Court has previously excluded "supplemental" opinions proffered by an expert on the grounds that those opinions were not included in the expert's initial report and were therefore untimely:

...Ethicon argues that Dr. Rosenzweig's fourth supplemental expert report is untimely because it includes a new opinion that the Abbrevio is a safer alternative design. I agree. This opinion is entirely new and was not contained in Dr. Rosenzweig's original report. It is, therefore, untimely and not substantially justified or harmless under Federal Rule 37(c). The parties cannot proffer new experts' opinions at this late stage on the eve of trial. I grant Ethicon's motion to exclude Dr. Rosenzweig's fourth supplemental expert report.⁴

Huskey v. Ethicon et al, 2:12-cv-05201 (S.D.W.Va.), 8/13/14 Pretrial Hearing Trans. at 4:22-5:6.

Moreover, Ethicon's effort to "supplement" Dr. Thames' opinions is clearly just an improper attempt to address the flaws of his cleaning protocol and exemplar testing that

² See Ex C, Supplemental Report of Dr. Thames (September 28, 2016).

³ Ex. D, Report of Dr. Thames in Wave 1 (March 1, 2016).

⁴ Ex. E, *Huskey v. Ethicon et al*, 2:12-cv-05201 (S.D.W.Va.), 8/13/14 Pretrial Hearing Trans. at 4:22-5:6.

Plaintiffs contest in their recent *Daubert* motions. *See Luna Corp. v. Stryker Corp.*, 226 F.R.D. 536, 542 (S.D. W. Va. 2005) (“Rule 26(e) . . . does not cover failures or omission because the expert did an inadequate or incomplete preparation. To construe supplementation to apply whenever a party wants to bolster or submit additional expert opinions would [wreak] havoc in docket control and amount to unlimited expert opinion preparation.”) (internal quotations omitted). Dr. Thames is not new to this litigation—he has been working on behalf of Ethicon for several years. There can be no reasonable justification for Dr. Thames’ untimely and supplemental opinions based upon his additional testing and analysis here.⁵ Moreover, the scientific reliability missing from Dr. Thames’ prior opinions (based upon his initial testing and cleaning) is not pardoned by his attempt to fix or “supplement” those opinions with new testing. He does not get a *do-over*.

In the alternative, Plaintiffs ask the Court for the opportunity to file an additional *Daubert* motion to address the opinions and methodology contained in both of his Supplemental Reports—because they are patently flawed in several respects. The most obvious being that even though this new testing and analysis was intended to counter Plaintiffs’ complaints about Dr. Thames’ abrasive cleaning protocol, he made no attempt to take the phenomenon of *in vivo* surface oxidation into account, even though this is where the peer reviewed literature states that Prolene oxidation is actually taking place:

Because this [oxidative] cracking is confined to the outer skin, which is clearly distinguishable from the inner core structure, it is not surprising to observe that,

⁵ Defendants’ failure to timely serve Dr. Thames’ report is neither “substantially justified” nor “harmless.” *See, e.g., Luna Corp.*, 226 F.R.D. at 544 (Courts should assess the “substantial justification” and “harmful” factors under the five-part *Southern States* test in considering whether the reports should be excluded.); *Wickline v. United States*, No. 5:05-0024, 2006 U.S. Dist. LEXIS 97279, *9 (S.D. W. Va. Nov. 8, 2006).

during abrasive stresses, such as cleaning, there was a tendency for the cracked rings at the surface to flake off and separate from the underlying core material.⁶

Instead, Dr. Thames oxidized a sample of TVT in its *entirety* by using ultraviolet light—to the point where the sample crumbled apart—and then he analyzed that sample to show that it was oxidized.⁷ But the fact that the entire sample was oxidized means that every analysis he performs here is going to show evidence of oxidation, no matter how much surface material is removed by the various steps of his destructive cleaning protocol.

Plaintiffs have never alleged—nor does the literature provide—that what Dr. Thames has done here is representative of what happens to polypropylene in the human body. As such, the testing discussed in Dr. Thames’ Supplemental Reports, and any opinions he garnered from them, do not address Plaintiffs’ argument that his cleaning protocol destroys evidence of oxidation on explanted meshes. Therefore, not only are Dr. Thames’ new opinions untimely, they are also irrelevant and unreliable. As such, should the Court not find it appropriate strike these opinions as untimely, Plaintiffs request the opportunity to file a supplemental *Daubert* brief to exclude them at trial.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court enter an order striking Dr. Thames’ Supplemental Reports from the record and precluding him from offering any testimony concerning the opinions or testing described therein. If the Court denies that request, Plaintiffs ask for the opportunity to address the flaws inherent to Dr. Thames’ opinions and methodology in his Supplemental Reports through a subsequent *Daubert* motion.

⁶ Exhibit F, Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louise Martin, Robert Guidoin, *Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery*, ASAIO Journal, 44 (1998) 199-206.

⁷ Ex. B, Supplement Report of Dr. Thames at 11.

Dated: October 6, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 6, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/Edward A. Wallace